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REMARKS

Claims 1-11 are pending in the instant application. Claims 1-11 have been rejected. Claims 1 and 11 have been amended to place these claim in better form for consideration by clarifying the beneficial effect of the compositions. Support for this amendment is found in claim 8 as originally filed. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Rejection of Claims Under 35 U.S.C. §103

Claims 1-3 and 6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,902,578 (Halpin-Dohnalek et al.) for the reasons of record. Applicant respectfully traverses this rejection.

Halpin-Dohnalek et al. teach at column 3, lines 42-46, a powdered nutritional product composed of:

"protein, fat, carbohydrates, minerals, vitamins, trace elements and a probiotic system, said probiotic system comprising *Lactobacillus reuteri*, *Lactobacillus acidophilus*, and *Bifidobacterium infantis*."

However, the only exemplification of a nutritional product is provided in Example 1, which teaches flavor packets containing a culture mix composed of 5×10^{10} CFU/g *Lactobacillus reuteri*, 5×10^{10} CFU/g *Lactobacillus acidophilus*, and $6-7 \times 10^{10}$ CFU/g *Bifidobacterium infantis* blended with either sucrose and cocoa powder; or sucrose, dextrose and vanilla flavor. In this regard, the probiotic component is the only component of any composition disclosed by Halpin-Dohnalek et al. for which a specified amount is provided.

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A *prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. *In re Bell*, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). An obviousness analysis requires that the prior art both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art. *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

While the Examiner concludes that "it would have been obvious to one of ordinary skill in the art to optimize the amounts of components and water content of the composition of the cited reference with a reasonable expectation of successfully obtaining the reference composition", such a conclusion is not well-founded. To begin with, there is nothing in the teachings of Halpin-Dohnalek et al. which would have suggested modifying the compositions disclosed therein for any palpable reason, nor has the Examiner proffered such a reason.

In addition, and in contrast with the Applicant's disclosure, the teachings of Halpin-Dohnalek et al. lack any teaching or suggestion of specific amounts of components and water content whose optimization would be within the skill of the art. In fact, there is absolutely no direction or guidance provided by this reference as to a starting point from which to optimize the amount of carbohydrate, fat, protein and water activity to arrive at the claimed composition.

In effect, the instant rejection says that it would have been obvious to vary the composition of Halpin-Dohnalek et al., even though the prior art gives no indication of what components

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or amounts of components are essential and no direction as to what modifications in the composition would likely be successful in producing a nutritional food or nutritional food product which maintains or enhances gastrointestinal health. This is not obviousness under §103, but rather an "obvious-to-try" rejection, as discussed in *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988): "In some cases, what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful."

Accordingly, the statements made by the Examiner amount to no more than convenient assumptions about what would have been obvious to the skilled artisan at the time of the invention. However, under MPEP §2144.03, it is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697. See also *In re Thrift*, 298 F.3d 1357, 1364, 63 USPQ2d 2002-2006 (Fed. Cir. 2002) (quoting *Lee*, 277 F.3d at 1344-45, 61 USPQ2d at 1435) (reliance on "common knowledge and common sense" do not fulfill the requirement to provide reasons in support of the findings of obviousness"). Therefore, the Examiner has not established a *prima facie* case of obvious under 35 U.S.C. 103(a) and it is respectfully requested that this rejection be reconsidered and withdrawn.

Claims 1, 3-6 and 8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,085,874 (Jungvid)

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for the reasons of record. Applicant respectfully traverses this rejection.

Jungvid teaches a feed-stuff for young animals which has an "ideal composition and taste, without disturbing the gastrointestinal functions of the animals" (see column 1, lines 26-30). The feed-stuff disclosed by Jungvid is high in fat (30-36% by weight) and protein (18-26% by weight of whey, 3-8% by weight of casein, 6-10% by weight of vegetable protein, 10-32% by weight of animal protein) and low in carbohydrate (2-15% by weight starch, 1% by weight dextrose) content. See claim 1 at column 4. In contrast, the instant composition is high in carbohydrate (47-82% by weight) and protein (5-80% by weight) content and low in fat (2-12% by weight) content.

While the Examiner generalizes that "it would have been obvious to one of ordinary skill in the art to optimize the amounts of components and water content of the composition of the cited reference with a reasonable expectation of successfully obtaining the reference composition", the Examiner has totally disregarded the desirability and thus the motivation for modifying the feed-stuff of Jungvid to arrive at the claimed composition.

"It is well-established that before a conclusion of obviousness may be made based on a combination of references, there must have been a reason, suggestion, or motivation to lead an inventor to combine those references." *Pro-Mold & Tool Co. v. Great Lakes Plastics Inc.*, 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996).

Although couched in terms of combining teachings found in the prior art, the same inquiry must be carried out in the context of a purported obvious "modification" of

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the prior art. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.

In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992).

In this regard, there is nothing in the teachings of Jungvid which would suggest modifying the compositions disclosed therein, and again the Examiner has not proffered such a reason. Applicant submits that there would be no rationale for the skilled artisan to optimize the feed-stuff composition of Jungvid to obtain the composition as presently claimed because the feed-stuff of Jungvid has an "ideal composition and taste", which when fed to young animals *does not disturb the gastro-intestinal functions of the animal*.

"The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis." *In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). In the instant case, the Examiner has not provided a factual basis for one of skill in the art to modify the composition of Jungvid to substantially reduce the fat content from 30-36% to 2-12% and substantially increase the carbohydrate content from 3-16% to 47-82% to meet the requirements of the instant composition. Thus, a *prima facie* case of obvious under 35 U.S.C. 103(a) has not been established. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

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Claims 1, 3-5, 7, 9 and 10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,744,134 (Paul) for the reasons of record. Applicant respectfully traverses this rejection.

Paul teaches that an improvement and maintenance of gastrointestinal health can be achieved with an immunoglobulin composition comprising:

"an immunoglobulin preparation containing immunoglobulins that bind and inactivate pathogenic microorganisms in the gastrointestinal tract and soluble dietary fiber that provides the typical advantages of dietary fiber and additionally is low in calories, does not affect blood glucose or insulin levels, and favors the growth of beneficial bacteria in the gastrointestinal tract while at the same time inhibiting the growth of potentially pathogenic or harmful microorganisms."

See column 3, lines 18-28. Paul teaches that the disclosed composition can *optionally* contain 0-20% by weight of beneficial human intestinal bacteria (see column 13, lines 17-33) and be provided in the form of a *powder or liquid* (see the paragraph spanning columns 13 and 14).

Although the Examiner acknowledges that Paul is silent to the claimed amounts of each component or wherein the water content is less than about 4.7, the Examiner alleges that because Paul teaches that the composition of the mixture can be varied, "it would have been obvious to one of ordinary skill in the art to optimize the amounts of components and water content of the composition of the cited reference with a reasonable expectation of successfully obtaining the reference composition." This general conclusion does not, however, constitute a factual basis for a rejection under 35 U.S.C. 103(a). Cf. *In re Warner*, 379

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F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057.

In actuality, Paul does not disclose any fact or notion for providing high titers (e.g., 5 to 20 billion CFU) of viable probiotics to the gastrointestinal tract and achieving a water activity of less than about 0.47. In fact, Paul explicitly indicates that

"other ingredients are optional components of the invention. What is required is that the immunoglobulin composition contain an 'effective amount' of immunologically active immunoglobulins."

See column 5, lines 55-60. As such, Paul provides no appreciation that probiotic titer and water activity are result effective variables which the skilled artisan would optimize to achieve the result of restoring or maintaining gastrointestinal health.

In contrast, Applicant has appreciated that a food or nutritional product containing a high number of probiotic bacteria, ranging from about 5 to 20 billion CFU's, provides not only good gastrointestinal health and overall well-being, but also a greater propensity to hydrolyze toxic nitrogenous waste products. See page 13, lines 23-28. Moreover, the claimed compositions are an improvement over existing probiotic compositions which are "prone to loss in viability due to their greater susceptibility to moisture, light, oxygen and heat," in that the claimed compositions provide a solid, low-moisture nutritional food or nutritional product with a water activity of less than about 0.47. See page 14, lines 15-24, and page 19, lines 11-17.

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The courts have held that a particular parameter must first be recognized as a result-effective variable, *i.e.*, a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In so far as the composition of Paul can optionally contain 0-20% of a beneficial human intestinal bacterium and be in either powder or liquid form, it is clear that Paul does not consider these elements to be essential variables which could be varied to achieve the intended result of restoring or maintaining gastrointestinal health.

Because the Examiner has not provided any compelling evidence of record to support the conclusion that it would have been obvious to optimize variables which are considered *optional* to the composition of Paul, the Examiner has not met the initial burden of establishing why the prior art, relied on, would have led one of ordinary skill in this art to arrive at the claimed compositions. Thus, the statements made by the Examiner amount to no more than conclusory statements about skilled artisans. However, such statements are inadequate to support a *prima facie* case of obvious under 35 U.S.C. 103(a). It is therefore respectfully requested that these rejections be withdrawn.

Claims 1-5, 7, 10 and 11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,518,740 (Costanzo et al.) for the reasons of record. Applicant respectfully traverses this rejection.

Costanzo et al. disclose a general process for preparing yogurt-based freeze-dried foodstuffs. This reference teaches that the process provides on the order of $10-10^6$ living milk ferments.

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See column 11 (lines 9-11), column 12 (lines 19-20) and column 14 (line 15). Costanzo et al. provide five specific recipes for such freeze-dried foodstuffs in Examples 1-4. In particular, this reference teaches the inclusion of 0.1-0.2% soya lecithin as an optional ingredient in three of the five recipes.

The Examiner acknowledges that Costanzo et al. do not teach the claimed amounts of each component or wherein the water content is less than about 4.7. However, it is alleged that because Costanzo et al. teach a water level of 3-8% and that the composition of the mixture can be varied, "it would have been obvious to one of ordinary skill in the art to optimize the amounts of components and water content of the composition of the cited reference with a reasonable expectation of successfully obtaining the reference composition." However, the Examiner has not indicated what effect the optimization is to achieve. Again, this general conclusion does not constitute a factual basis for a rejection under 35 U.S.C. 103(a). *Cf. In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057.

Applicant has appreciated that by mixing a fat with viable probiotic bacteria, loss in viability is minimized or prevented. See page 19, lines 19-24, and the paragraph bridging pages 16 and 17. By preventing a loss in viability, Applicant's composition provides 5 billion to 20 billion CFU of probiotic bacteria which are good for gastrointestinal health and overall well-being, as well as the hydrolysis of toxic nitrogenous waste products. See page 13, lines 23-28. The compositions of Costanzo et al. are not disclosed as having any such therapeutic benefits.

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Thus, the fat component of the present composition set forth in claim 1 is a result-effective variable which prevents or minimizes the loss in viability of the probiotic component. Given that the 0.1-0.2% soya lecithin of Costanzo et al. is an *optional* component, it cannot be held as a result-effective variable which would have directed one of ordinary skill in the art specifically to the claimed 2-12% amount of fat for providing 5 to 20 billion CFU probiotic bacterial titers.

Moreover, as indicated throughout the instant disclosure, the inclusion of 5-20 $\times 10^9$ CFU of probiotic bacteria in the claimed compositions alleviates the symptoms of uremia and maintains or enhances gastrointestinal health. Because the yogurt-based freeze-dried foodstuffs of Costanzo et al. are not disclosed as having any therapeutic benefit, there would be no motivation for the skilled artisan to conduct the extensive experimentation to increase the number of viable bacteria by three orders of magnitude to arrive that the probiotic bacterial titers of the present compositions.

As indicated *supra*, the mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification. *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992). In the instant case, neither the prior art nor the Examiner has provided any rationale for modifying the amount of fat or probiotic bacteria of Costanzo et al. to that which is set forth in the present claims. Thus, a *prima facie* case of obvious under 35 U.S.C. 103(a) has not been established. It is therefore

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respectfully requested that this rejection be reconsidered and withdrawn.

II. Conclusion

The Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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